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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,129	03/29/2004	David G. Whitten	8971-039-27 DIV	2489

7590 12/28/2004
Supervisor, Patent Prosecution Services
PIPER RUDNICK LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,129

Applicant(s)

WHITTEN ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 19 and 20, drawn to method of detecting a target biological agent in a sample, classified in class 436, subclass 518.
 - II. Claims 21 and 22, drawn to a method of determining the presence of a target chemical ligand in a sample, classified in class 435, subclass 7.93.
 - III. Claims 23-33, drawn to an assay reagent, classified in class 548, subclass 304.7.
 - IV. Claims 34 and 35, drawn to a method of detecting a target biological agent in a sample, classified in class 436, subclass 501.
 - V. Claims 36 and 37, drawn to a method of detecting first and second target biological agents in a sample, classified in class 435, subclass 973.
 - VI. Claims 38-41, drawn to a compound and a kit, classified in class 436, subclass 546.
2. Inventions I and II are independent and distinct inventions. Invention I is a method involving applying an electric field and detecting a difference in fluorescence emitted after the electric field is applied compared with that emitted in the absence of the electric field and Invention II does not require these limitations. Further, Invention II requires permitting the target chemical ligand to compete with the chemical moiety for the binding of the bioagent and Invention I does not require these limitations.

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3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention II.

4. Inventions I and IV are independent and distinct inventions. Invention I is a method involving applying an electric field and detecting a difference in fluorescence emitted after the electric field is applied compared with that emitted in the absence of the electric field and Invention IV does not require these limitations. Further, Invention IV requires

5. Inventions I and V are independent and distinct inventions. Invention I is a method involving applying an electric field and detecting a difference in fluorescence emitted after the electric field is applied compared with that emitted in the absence of the electric field and Invention V does not require these limitations. Further, Invention V requires first and second fluorescent polymers and Invention I does not require this limitation.

6. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions II or IV.

7. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I.

8. Inventions II and IV are independent and distinct inventions. Invention II requires a chemical moiety and also requires permitting the target chemical ligand to compete with the chemical moiety for the binding of the bioagent and Invention IV does not require these limitations.

9. Inventions II and V are independent and distinct inventions. Invention II requires a chemical moiety and also requires permitting the target chemical ligand to compete with the chemical moiety for the binding of the bioagent and Invention V does not require these limitations. Further, Invention V requires first and second fluorescent polymers and Invention II does not require this limitation.

10. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I or Invention V.

11. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I or Invention V.

12. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I or IV.

13. Inventions III and VI are independent and distinct inventions. Invention III is a reagent comprising a mixture of first and second polymers whereas Invention VI is a compound requiring a recognition element and a property-altering element bound together by a tethering element. Further, the recognition element comprises a peptide nucleic acid and Invention III does not require these limitations.

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14. Inventions IV and V are independent and distinct inventions. Invention V requires first and second fluorescent polymers and first and second bioconjugates and Invention IV does not require these limitations.

15. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I or Invention V.

16. Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Invention I or Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

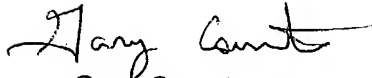
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Gary Counts

Examiner

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December 23, 2004



LONG V. LE

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600

12/21/04